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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MALLARI, PATRICIA C	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/659,617	THEDE ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,7-9,11-17 and 19-24* is/are rejected.

7)☒ Claim(s) *3,4,6,10 and 18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 September 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/10/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the flexible ring in the housing unit for equalizing pressure around the pressure sensor, as claimed in claim 18 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Claim 18 recites that the housing unit comprises a flexible ring for equalizing pressure around the pressure sensor. However, the specification lacks sufficient antecedent basis for the limitation in the claim. The instant application shows the pressure sensor comprising a flexible ring 64 for equalizing pressure around the pressure sensor, but fails to teach such a ring as being part of the housing unit (fig. 4B; pp. 12, lines 11-12 of the specification).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, and 5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of US Patent No. 6,695,789 to Thede et al., herein referred to as patent '789. The conflicting claims are not identical. However, the claims are not patentably distinct from each other. Claim 6 of patent '789, which is dependent upon claim 1 of the patent, recites all of the structural limitations of claim 1 of the instant application except that claim 1 of the instant application recites, "a base unit for pivotally attaching to the blood pressure measurement device" while claim 6 of patent '789 recites "a base unit pivotally connected to the housing unit". It is clear that the "housing unit" recited on line 4 of claim 1 of patent '789 is part of the blood pressure measurement device of claim 1; therefore, the base unit of claim 6 of patent '789 is pivotally connected to the blood pressure measurement device.

Regarding claim 2 of the instant application, claim 5 of patent' 789, upon which claim 6 depends, recites that the connecting means comprises a plurality of electrical

connectors connected to the transducer, wherein the transducer is an element of the sensing means, and the connectors are received by a receptacle of the base unit.

Claim 11 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of patent '789. Although the conflicting claims are not identical, they are not patentably distinct from each other because the body of claim 1 of patent '789 recites all of the structural limitations of claim 11 of the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7, 12, 13, 15-17, 19, 20, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated over US Patent No. 5,941,828 to Archibald et al., herein referred to as Archibald '828. Archibald '828 describes a sensor interface assembly for a blood pressure measurement device. The device comprises a housing unit 14, a base unit 22 pivotally connected to the housing unit 14 and including electrical circuitry 24, 26, 30 interconnected with the housing unit 14, and a sensing unit 30 for sensing pulses of the underlying artery and detachably connected to the base unit 22 (figs. 1, 3a & 3b; col. 4, lines 36-49; col. 5, lines 20-23; col. 6, lines 7-14 of Archibald '828).

Regarding claims 12, 13, 15-17, 19, 20, and 24, the measurement device comprises a housing unit 14 including a receptacle (fig. 1 of Archibald '828). The receptacle is not identified by a reference numeral in figure 1 but is shown as receiving plug 26. A pressure sensor 22 non-invasively senses blood pressure pulses in an artery and is detachably connected to the housing (figs. 1, 3a, 3b; col. 4, lines 9-12; col. 4, lines 50-52; col. 6, lines 7-14 of Archibald '828). The pressure sensor 22 includes a plug 26 for mechanical and electrical connection to the receptacle (figs. 1 & 3a; col. 5, lines 20-23 of Archibald '828).

With further regard to claims 13 and 20, the plug comprises an electrical connector, which connector is received by the receptacle (fig. 1; col. 5, lines 20-23 of Archibald '828).

With further regard to claims 15-17, the pressure sensor 22 comprises a pressure transducer 30 having a sensing surface for sensing pulses of the underlying artery, a flexible diaphragm 168 having an active portion 168b for transmitting blood pressure pulses of the underlying artery, and interface means 208, 210, 276 coupled between the sensing surface of the transducer 30 and the flexible diaphragm 168 for transmitting the blood pressure pulses within the underlying artery from the flexible diaphragm 168 to the sensing surface of the transducer 30 (fig. 3B;col. 6, lines 7-46; col. 8, lines 8-21 of Archibald '828).

With further regard to claim 16, the interface means comprises a fluid coupling medium (col. 8, lines 8-21 of Archibald '828).

With further regard to claim 17, a compressible side wall 164 surrounds the active portion 168b and conforms to the anatomy surrounding the underlying artery (fig. 3B; col. 8, lines 42-55 of Archibald '828).

With further regard to claim 24, the housing unit 14 comprises electrical circuitry that receives output signals corresponding to sensed pressure data from the pressure sensing unit 22 and transmits the output signal to a microprocessor where a blood pressure value is derived (fig. 2; col. 5, lines 20-64 of Archibald '828).

Claims 12, 13, 19, 20, 22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,081,742 to Amano. Amano discloses a non-invasive blood pressure measurement device for determining blood pressure of an artery. The device comprises a housing unit 100 including a receptacle 105 and a pressure sensor 102, 104 for non-invasively sensing blood pressure pulses in the artery, the pressure sensor 102, 104 being detachably connected to the housing and including a plug 106 for mechanical and electrical connection to the receptacle 338 (figs. 1, 10, and 11; col. 8, lines 4-52; col. 9, line 65-col. 10, line 2; col. 13, line 63-col. 14, line 28; of Amano).

Regarding claims 13 and 20, the plug further comprises an electrical connector, the connector being received by the receptacle 105 (figs. 1 & 10; col. 9, line 65-col. 10, line 2 of Amano).

Regarding claim 22, the electrical connector provides power to the pressure sensing unit and receives output signals from the sensor (col. 9, line 65-col. 10, line 2 of Amano).

Regarding claim 24, the housing unit further comprises electrical circuitry that receives output signals corresponding to the sensed pressure data from the pressure sensing unit 102, 104 and transmits the output signals to a microprocessor 181 where a blood pressure value is derived (figs. 1, 5; 10, and 11; col. 9, line 65-col. 10, line 2; col. 13, line 63-col. 14, line 28, of Amano).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12, 13, 15-17, 19, 20, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,649,542 to Archibald et al., herein referred to as Archibald '542, in view of Archibald '828. Archibald '542 teaches a non-invasive blood pressure measurement device comprising a housing unit 22 and a pressure sensor 24 for non-invasively sensing blood pressure pulses in an artery detachably connected to the housing 22 (figs. 3 & 4; col. 3, lines 10-61; of Archibald '828). The housing 22 and sensor 24 are mechanically and electrically coupled, but the coupling means is not explicitly described.

However, Archibald '828 teaches a non-invasive blood pressure measurement device wherein the pressure sensing unit 22 and the housing unit 14 are coupled via a plug 26 that electrically and mechanically couples the two units (figs. 1, 2, and 3A of

Archibald '828). Figure 1 of Archibald '828 shows a receptacle interconnected with the housing unit 14 and receiving the plug 26. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the coupling means of Archibald '828 as that of the device of Archibald '542, since Archibald '542 teaches coupling the housing unit and the pressure sensing unit, and Archibald '828 describes an appropriate means of doing so.

Regarding claims 13 and 20, the plug 26 comprises an electrical connector (col. 5, lines 20-24 of Archibald '828).

Regarding claims 15-17, the pressure sensor 24 comprises a pressure transducer 96 having a sensing surface for sensing pulses of the underlying artery, a flexible diaphragm 74 having an active portion for transmitting blood pressure pulses of the underlying artery, and interface means76 coupled between the sensing surface of the transducer 96 and the diaphragm 74 for transmitting the blood pressure pulses form the diaphragm 74 to the active surface of the transducer 96 (figs. 3 & 4; col. 6, line 58-col. 7, line 25; col. 8, lines 5-14 of Archibald '542).

With further regard to claim 16, the interface means comprises a fluid coupling medium (col. 6, line 65-col. 7, line 6 of Archibald '542).

With further regard to claim 17, a compressible side wall 70 surrounds the active portion and conforms to the anatomy surrounding the underlying artery (Figs. 3 & 4; col. 5, line 65-col. 6, line 52; col. 7, lines 7-25)

Regarding claim 23, the housing unit 22 further comprises a drive assembly 22, 38 connectable to the pressure sensing unit 24 for applying force to cause the sensor 74, 96 to be pressed against the artery (figs.1-3; col. 3, lines 52-55 of Archibald '542).

Regarding claim 24, the housing unit 24 comprises electrical circuitry that receives output signals corresponding to sensed pressure data from the pressure sensing unit 24 and transmits the output signal to a microprocessor where a blood pressure value is derived (fig. 2; col. 3, line 52-col. 4, line 46 of Archibald '542).

Claims 8, 9, 14 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Archibald '828, as applied to claims 7, 12, 13, 15-17, 19, 20, and 24 above, and further in view of US Patent No. 4,632,121 to Johnson et al. Archibald '828 is silent as to the details of the plug. However, Johnson describes a plug for a medical device comprising a plurality of electrical connectors 42, 44, 46 (fig. 2 of Johnson). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the plug and receptacle construction of Johnson as that of Archibald '828 since Archibald '828 teaches using a plug and receptacle and Johnson describes an appropriate such plug and receptacle and further to ensure matching of the plug and receptacle to prevent any erroneous connection (col. 4, lines 17-20 and lines 30-35 of Johnson).

Regarding claims 8, 9, 14, and 21, the plug employs alignment elements, comprising terminal pins 42, 44, 46 and a perimeter configuration of the recesses 38, 40, in a plug comprising an electrical connector for a medical device, wherein the

alignment elements align the electrical connector with a corresponding receptacle (figs. 2, 7; col. 4, lines 11-20 of Johnson).

Allowable Subject Matter

Claims 1, 2, 5, and 11 would be allowable if the double patenting rejection set forth in this Office action were overcome.

Claims 3, 4, 6, 10, and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

With regard to claims 1-6, the prior art of record fails to teach or fairly suggest a sensor interface assembly for a blood pressure measurement device comprising a base unit for pivotally attaching the blood pressure measurement device and a means for detachably connecting the sensing unit to the base unit wherein the means for detachably connecting mechanically and electrically couple the sensing unit to the base unit, in combination with all of the other limitations of the claims. The language "means for detachably connecting the sensing unit to the base unit" on lines 9-10 of claim 1 meets the 3-prong test per MPEP 2181 and thereby invokes 35 U.S.C. 112, 6th paragraph. The means for detachably connecting the sensing unit to the base unit is described in the specification as an alignment element 36 and electrical connectors 38 which are received by a receptacle in the base unit (see lines 14-21 of p. 8 and figure 3

of the instant specification). The claim language, therefore, is limited to the connecting means as described by the specification and its equivalents. Similarly, the language "sensing means for sensing a blood pressure of each pulse . . ." on lines 6-9 of claim 1 meets the 3-prong test, thereby invoking 35 U.S.C. 112, 6th paragraph and is limited to the pressure transducer, diaphragm, and fluid coupling medium based sensor described in figure 5B and on lines 13-19 of the instant specification and its equivalents.

Regarding claim 10, the prior art of record fails to teach or fairly suggest a non-invasive blood pressure measurement device for determining the blood pressure of an artery, the device comprising a sensing unit including a plurality of electrical connectors which are received by a receptacle of the base unit and which provide power to the sensing unit as well as receive output signals from the sensing means, wherein the base unit is pivotally coupled to the housing unit, in combination with all of the other limitations of the claim.

Regarding claim 11, the prior art of record fails to teach or fairly suggest a sensor for a non-invasive blood pressure measurement device comprising a base unit for coupling to the blood pressure measurement device and including a flexible ring and a connection receptacle and the sensor further comprising a sensing unit comprising a pressure transducer, flexible diaphragm, interface means, compressible ring and connecting means for detachably connecting the sensing unit to the receptacle of the base unit, in combination with all of the other limitations of the claim. The language "connecting means for detachably connecting the sensing unit to the base unit" on the final two lines of claim 11 meets the 3-prong test per MPEP 2181 and thereby invokes

35 U.S.C. 112, 6th paragraph. The means for detachably connecting the sensing unit to the base unit is described in the specification as an alignment element 36 and electrical connectors 38 which are received by a receptacle in the base unit (see lines 14-21 of p. 8 and figure 3 of the instant specification). The claim language, therefore, is limited to the connecting means as described by the specification and its equivalents.

Regarding claim 18, the prior art of record fails to teach or fairly suggest a non-invasive blood pressure measurement device for determining the blood pressure of an artery comprising a housing unit that further comprises a flexible ring for equalizing pressure around the pressure sensor, in combination with all of the other limitations of the claim.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 4,305,401 to Reissmueller.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Mallari
Patent Examiner
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